

Appl. No. : 09/582,817  
Filed : November 8, 2000

### REMARKS

Claims 35-39 and 46 have been canceled. Claims 30 and 43 have been amended. Support for the amendments can be found in the Specification as filed. In particular, the amendments are support at page 5, lines 15-24; page 12, lines 19-30; page 16, lines 20-27; page 18, lines 8-12; page 18, lines 24-32; page 19, lines 1-5; page 21, lines 3-13; page 23, lines 31-32; page 24, lines 1-3; page 25, lines 7-12; page 28, lines 2-3; page 28, lines 12-20 and Claims 39 and 46. Therefore, no new matter has been introduced herewith. Claims 30, 31, 34, 40, 41, 43-45 and 47 are pending. The following addresses the substance of the Final Office Action.

#### **Claim rejection under 35 U.S.C. §112**

The Examiner has rejected Claims 30, 31 and 34-47 under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement. More specifically, the Examiner has interpreted the independent Claim 30 as encompassing performance of any part of the assay while at the same time having the disc rotate at any speed, and while the detection and binding areas are located in grooves. Furthermore, the Examiner asserts that the disclosure is limited to supports of particular dimensions.

The Applicant has amended Claim 30 to additionally recite: a compact disc (CD) or DVD comprising registered data that can be read by a CD reading device, supported in the Specification as filed on page 5, lines 15-16 and in now canceled Claim 46. Support for the preferred embodiments of the disc dimensions is found on page 12, lines 8-12. However, on page 4, line 23 through page 5, line 7 the broad definition of the "disc" is described as a "flat solid support... which comprises a hole that allows its rotation according to an axis which is located in the center of said hole, made in a rigid material". As discussed in the specification, the exact dimensions of the CD or DVD disc are irrelevant to the method of detection of the invention.

The Applicant has further amended Claim 30 to recite: "registered data that can be read by a CD reading device", supported in the Specification on page 5, lines 15-18.

The Applicant has further amended Claim 30 to recite: "wherein said binding occurs in areas separated from areas comprising registered data". The binding may occur in grooves or in other areas that do not comprise registered data. Separation of the biological molecules from the registered data reduces interference between the two types of information and permits two different reading devices to be utilized to read the two signals.

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The Applicant has further amended Claim 30 to recite: "treating said CD or DVD in order to obtain a detectable signal resulting from the binding of the target molecule and said capture molecule, wherein said binding results in a precipitate on said CD or DVD", supported in the Specification on page 16, lines 20-27, page 28, lines 2-3 and 12-20. This step clearly separates the binding of the target molecule (on a non-moving disc) thereby creating a signal in the form of a precipitate (See pages 26-31 of the Specification, page 23, lines 31-32, page 24, lines 1-3, and Claim 39 now canceled) from the next step of detecting the signal by the reading device which requires rotation of said disc.

With respect to the Examiner's assertion that the only device used to detect the signal was artisan's eyes, Applicant notes that the picture for the disc post color development was provided in order to show how the CD looks after detecting the biological molecules on the CD. The provided picture is the digitalized results obtained from reading the CD using the device described in the specification. To clarify this point, the Applicant has further amended Claim 30 to recite: "said readings being done in an apparatus comprising two different reading devices".

Therefore, the now amended Claim 30 is supported in the Specification as filed and withdrawal of the rejection of Claims 30, 31 and 34-47 under 35 U.S.C. §112, first paragraph is specifically requested.

#### **Claim rejection under 35 U.S.C. §103**

The Examiner has rejected Claims 30, 31, 35-47 under 35 U.S.C. §103(a) as being allegedly obvious over Virtanen (USP 6,030,581) in view of Rushbrooke et al. (USP 6,263,095 B1). More specifically, the Examiner alleges that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the method of detection disclosed by Rushbrooke et al. with that of Virtanen to use fluorescent labels and detection of same via a CD reader. The Applicant respectfully disagrees.

To establish a *prima facie* case of obviousness, the PTO must cite one or more references that provide some suggestion or motivation to modify the references to achieve the claimed invention, provide a reasonable expectation of success to achieve the claimed invention, and finally, the cited art must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Here, the cited art either taken alone or in combination, fails to provide any of the required factors.

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Here, Virtanen teaches a disc platform for performing an integrated assay where all chemistry (mixing, washing, reacting, etc.) is performed inside the disk. Centrifugal force is the main force used to transfer liquids in the integrated bio-compact disk of Virtanen by using the rotation of the disk to spread fluids into the channels. Thus, the disk provided in the Virtanen reference is not a conventional CD or DVD but instead is a disk comprising multiple layers and elements such as microchannels or chambers which are in fluidic contact with one another. Further, in the Virtanen reference the assay is performed by mixing the components on a rotating disk while in the presently claimed methods the disk is not rotating when the binding step is performed.

Furthermore, in Virtanen, the detection of the analyte is obtained through the cleavage of capture molecules, therefore is indirect. In contrast, the present claims specify that detection is not obtained indirectly through cleavage of capture molecules but rather is directly obtained from a precipitate.

Rushbrooke et al. fails to cure the deficiencies of Virtanen as it teaches method and apparatus by which light from a plurality of different points in a sample can be detected, mapped and quantified (direct detection of the signal): the label of Rushbrooke et al emits light, such as fluorescence. There is no motivation in the cited references to combine the indirect detection methods of Virtanen with the direct detection methods of Rushbrooke. Furthermore, in the currently claimed methods, the detectable signal is produced by a precipitate not by the emission of light as described in Rushbrooke.

For the foregoing reasons, Applicant maintains that the claimed methods are not obvious over Virtanen (USP 6,030,581) in view of Rushbrooke et al. (USP 6,263,095 B1), and withdrawal of the rejection of Claims 30, 31, 35-47 under 35 U.S.C. §103(a) is specifically requested.

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**CONCLUSION**

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, Applicants request the expeditious allowance of the pending claims.

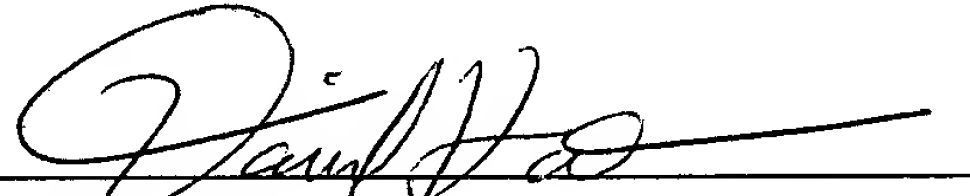
The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the undersigned at (619) 687-8633 (direct line), to discuss such issues.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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